UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,036	01/20/2004	William L. Dunbar JR.	DEP 5033NP	1189
27777 7590 03/15/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA			EXAMINER	
			HOFFMAN, MARY C	
	N & JOHNSON PLAZ WICK, NJ 08933-7003	A	ART UNIT	PAPER NUMBER
	·		3733	
	•		_	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MO	NTHS	03/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		$\gamma_{\mathcal{X}}$				
	Application No.	Applicant(s)				
Office Assistant Comment	10/761,036	DUNBAR ET AL.				
Office Action Summary	Examiner	Art Unit				
	Mary Hoffman	3733				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the o	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>28 February 2007</u> .						
,—						
3) Since this application is in condition for allowar						
closed in accordance with the practice under E	x parte Quayle, 1955 C.D. 11, 4	55 O.G. 215.				
Disposition of Claims		·				
, - ,	4)⊠ Claim(s) <u>1,4,5,7,9-11 and 15-20</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
· — · · · — · · · · — · · · · · · · · ·	5) Claim(s) is/are allowed.					
·) Claim(s) <u>1,4,5,7,9,11 and 15-20</u> is/are rejected.					
,	7)⊠ Claim(s) <u>10</u> is/are objected to. 8)□ Claim(s) are subject to restriction and/or election requirement.					
o, a.o a.a.,						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on 1/20/04,8,16,06 is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal					
Paper No(s)/Mail Date	6) Other:					

Application/Control Number: 10/761,036

Art Unit: 3733

DETAILED ACTION

The finality of the office action mailed 12/1/2006 has been withdrawn.

Allowable Subject Matter

Upon further consideration of the claims, the indicated allowability of claims 3, 4, 8-9 and 14-17 is withdrawn. The new rejections follow.

Claim Objections

Claims 1, 4-5 is objected to because of the following informalities:

In claim 1, lines 3 and 9, "distal end" should be changed to --distal end portion-to be consistent with the claim terminology.

In claim 4, line 3, "distal end" should be changed to --distal end portion-- to be consistent with the claim terminology.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 10/761,036

Art Unit: 3733

Claims 4, 11 and 15-20 rejected under 35 U.S.C. 102(b) as being anticipated by Becker (U.S. Patent No. 2,248,054).

Becker discloses a tool comprising a body (ref. #5) having a proximal end portion (top portion of ref. #5) and a distal end portion (bottom portion of ref. #5), the distal end portion including a first and second flexible branch (see branches separated by lateral opening ref. #8) capable of gripping a spinal implant, the flexible branches being biased to a closed position; an inserter shaft (FIG. 2, including ref. #'s 12, 21, 22, 23, 19, 26, 20) slidably received within the body, the inserter shaft having a distal end (ref. #20) capable of holding a closure mechanism for the implant; a threaded collar (ref. #17), adapted to couple the body and the inserter shaft, wherein the inserter shaft is capable of forcing a spinal rod into the rod-receiving portion of the implant (claim 4).

Becker further discloses a tool comprising a body (FIG. 4, ref. #5) having a proximal and a distal end portion, the distal end portion having branches (see branches separated by lateral opening ref. #8) capable of gripping a spinal implant, wherein an interior channel extends between the distal and proximal ends; an inserter shaft (FIG. 2) having a proximal and a distal end portion, the distal end portion capable of holding a closure mechanism for the spinal implant, wherein the shaft is sized to fit within the interior channel of the body; and a guide mechanism (pin, ref. #11 and corresponding channel, ref. #10) co-operable with the shaft and the body whereby the guide mechanism limits an independent movement of the shaft within the body, the guide mechanism including a channel and a pin adapted to fit within the channel, the channel located on the body and extending parallel to a longitudinal axis of the body, the pin

located on the shaft (claim 11). A portion of the channel branches off at an angle and reverses direction (see ref. #27) (claim 15). A point where the channel branches off corresponds to the point where the spinal rod is fully seated in the implant (claim 16). The angle is approximately 90 degrees (claim 17). The pin and channel prevent the shaft from being removed from the body [in the distal direction] (claim 18). The independent movement limited is a rotational orientation of the inserter shaft with respect to the body (claim 19). The independent movement limited is an axial translation of the inserter shaft with respect to the body (claim 20).

Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (U.S. Patent No. 5,649,931).

Bryant et al. disclose a tool comprising a body (ref. #14) having a proximal and distal end portion, wherein an interior channel extends between the distal and proximal end portions, said distal end portion having flexible branches (ref. #30) capable of gripping a spinal implant and said proximal end portion having external threads (ref. #38); an inserter shaft (ref. #16) slidable within said interior channel of the body having a proximal end portion (ref. #50), a distal end portion (ref. #34), and a transition zone located between said distal and proximal end portions, said transition zone having a diameter larger than the proximal end portions, said distal end portion capable of holding a closure mechanism for the spinal implant; and a collar (ref. #32,20) having an internally threaded hollow body (ref. #42) and a central shaft (ref. #20) attached to said hollow body, wherein said central shaft limits independent motion between said inserter shaft and said collar, wherein said diameter of the transition zone of the inserter shaft is

greater than an inner diameter (ref. #52) of the central shaft of the collar (claim 7). The gripping branches are biased in a closed position (claim 9).

Page 5

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison et al. (U.S. Patent 5,910,141).

Morrison et al. disclose a tool comprising a body (ref. #14, 18) having a proximal end portion and a distal end portion, said distal end including a first and second flexible branch (ref. #36/38) for gripping a spinal implant; an inserter shaft (FIG. 11b, ref. #88 and ref. #39) slidably received within said body, said inserter shaft having a distal end (ref. #88) adapted to hold a closure mechanism for said implant; a threaded collar (ref. #16), adapted to couple said body and said inserter shaft, wherein said inserter shaft forces a spinal rod into the rod-receiving portion of said implant, and an outer sleeve (ref. #12) rotatably and slidably mounted onto said distal end of said body, said outer sleeve movable between a first and second position, said body including a pin (ref. #24) projecting from said body and said outer sleeve has a channel for receiving said pin. The body further comprises external threads (ref. #28) to engage with the threaded collar.

Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 02/28/2007 have been fully considered but they are not persuasive.

With regard to the statement of intended use and other functional statements, e.g. "adapted to couple said body and said inserter shaft, wherein said inserter shaft forces a spinal rod into the rod-receiving portion of said implant," they do not impose any structural limitations on the claims distinguishable over the prior art, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

The rejections are deemed proper

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 $MCH \cap ()$

SUPERVISORY PATENT EXAMINER